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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,248	01/27/2004	Manoj Kumar Paruthi	1276-4	4167
<div>7590 04/20/2007 Michael E. Carmen, Esq. M.CARMEN & ASSOCIATES, PLLC Suite 400 170 Old Country Road Mineola, NY 11501</div>			<div>EXAMINER MAEWALL, SNIGDHA</div> <div>ART UNIT 1615 PAPER NUMBER</div>	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/20/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/766,248		PARUTHI ET AL.	
	Examiner		Art Unit	
	Snigdha Maewall		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/10/04 and 05/26/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Summary

1. Receipt of Information Disclosure Statements filed on 5/26/04 and 12 /10/04 is acknowledged.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because the Application Serial Number and the Date filed has been left blank in the first paragraph of the specification. Examiner suggests completing the Application Serial Number and the Date in order to claim priority.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 5 recites the limitation "polymethacrylic acid copolymer" where in the term polyacrylic acid signifies a homopolymer since the monomer is only methacrylic acid. This phrase is vague and indefinite because claim 5 is dependent on claim 3 which refers to a copolymer instead of a homopolymer. Does the expression mean polyacrylic acid is a block polymer in a block copolymer?

6. Claim 17 recites the limitation "wherein the one or more pharmaceutical additives is selected from.....agents". There is no antecedent basis for this limitation. Claim 14, on which claim 17 is dependent, does not recite any additives rather recites the "active pharmaceutical in the core". Examiner suggests correcting the dependency of the claim. For the purpose of the examination, the claim 17 has been interpreted as referring to claim 16.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-6, 9-10, 16-17, 20-21, 26-27, 30-34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 88/03795 ('795).

WO 88/03795 ('795) discloses a taste masked pharmaceutical composition comprising a core containing a pharmaceutically active agent coated with a polymer mixture comprising at least 5 wt.% of a high temperature film forming polymer and at least 5 wt.% of a low temp. film forming polymer. The high temperature film forming polymer is hydroxypropyl methylcellulose, hydroxypropylcellulose, ethylcellulose, polyvinyl alcohol, polyvinyl acetate, cellulose acetate butyrate or acrylic acid ester copolymers. The low temperature film-forming polymer is Eudragit E30D. The composition is chewable yet the taste is masked. Methacrylic acid copolymer is disclosed. WO 88/03795 ('795) further discloses that the polymeric coating may provide immediate release of active ingredient in stomach (page 7, lines, 26-35 and page 8, lines, 20-23 and 31-35). The composition comprises diluent or bulking agent in the core material such as dextrose, sorbitol lactose etc. (page 14, lines, 20-22). The bitter or unpleasant tasting drugs such as antibiotics, acetaminophen, dextromethorphan, or pseudoephedrin etc. can be coated in the formulation to mask the unpleasant taste (page 14, lines, 1-9). The method for producing taste-masked microcapsules comprises dispersing coating polymers and other additives and pressing into tablets (page 18, lines, 31-37).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 7-8, 11, 13, 15, 18-19, 23-25, 28-29 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/03795 ('795).

The teachings of WO 88/03795 ('795) have been discussed above. WO 88/03795 ('795) does not specifically teach the claimed percentages/ amounts of the active ingredients and polymeric film coating amounts. However, it is to be noted that with respect to the various percentages of active ingredient and polymeric coating amounts, it is the position of the examiner that such a parameter can be optimized and is within the purview of a skilled artisan, which can be attained with an experimental manipulation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

11. Claims 2, 12, 14 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/03795 ('795) in view of McTeigue et al. (US Pg. Pub. No. 2002/0031552 A1).

The teachings of WO 88/03795 ('795) have been discussed above. WO 88/03795 ('795) does not specifically teach active ingredient such as desloratadine.

McTeigue et al. discloses taste-masked particles and chewable tablets comprising core and a coat (abstract). The various active ingredients disclosed which have bitter or otherwise unpleasant taste include desloratadine in addition to other drugs such as

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acetaminophen, cetirizine, ranitidine or in a broader sense analgesics, antitussives and antihistamines etc. (page 2, paragraph [0013]).

Since the purpose of WO 88/03795 ('795) is to provide taste masked active ingredients by coating the bitter tasting or unpleasant tasting active ingredients, it would have been obvious to the one of ordinary skilled in the art at the time the invention was made to apply taste masked coating comprising ethyl cellulose and methacrylic acid copolymers in order to mask the bitter tasting desloratadine as McTeigue et al. discloses that desloratadine is one of the drugs which is bitter tasting in nature. A skilled artisan would thus have been motivated to formulate a taste-masked dasloratadine composition with a reasonable expectation of success. It is to be noted that with respect to the various percentages of active ingredient, it is the position of the examiner that such a parameter can be optimized and is within the purview of a skilled artisan, which can be attained with experimental manipulation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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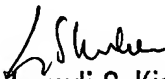
number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

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Gollamudi S. Kishore, PhD
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